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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/797,214	02/07/97	ROUBIN G	PAT-1129

33M1/1030

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EXAMINER	
REIP,D	
ART UNIT	PAPER NUMBER
3309	

DATE MAILED: 10/30/97

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.	Applicant(s)
08/797,814	Roubin et al.
Examiner	**Group Art Unit**
David O. Reip	3309

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-32* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-27, 29, and 32* is/are rejected.

☒ Claim(s) *28, 30, and 31* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. With respect to claims 1 and 12, it is apparent to this examiner that unless the ends of the stent are somehow constrained, the stent will not maintain a consistent length between the compressed and expanded states, i.e. when viewing Fig. 6B, it is not seen how the wave-shaped connecting members alone will elongate to compensate for the reduction in the longitudinal dimension of the annular elements when the annular elements are expanded, except by pulling the ends of the stent apart as the stent is expanded. The only configuration which this examiner believes would function as claimed would be manufacturing the stent of a shape memory alloy (i.e. Nitinol) so that the expanded shape of the stent, to include the length, could be "preset". The stent could then be compressed while constraining the ends to maintain a constant length, which would result in the connecting members being compressed or "buckled" as seen in Fig. 6B. Upon heating the compressed stent, it would return to the expanded state while maintaining a constant length. However, none of the above is disclosed in the specification other than the possible choice of Nitinol as one of several alternatives for the material of manufacture.

2. Claims 3 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 3, line 1, "members" lacks antecedent basis. With respect to claim 9, lines 2-3, "a higher amplitude and a smaller wavelength" lacks antecedent basis. Also with respect to claim 3, the claim is unclear because the word "than" in line 3 causes the reader to believe that the connecting member is shaped to have a higher amplitude and smaller wavelength in the expanded state as compared to the compressed state, when in actuality the inverse is true.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-13, 16-19, 22-27, 29 and 32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pinchasik et al (U.S. Pat No. 5,449,373). Figs. 3A-3C of Pinchasik et al show a stent 122 having all the limitations as recited in the above claims, including: (with respect to claims 1-11) a plurality of annular elements 102 and connecting members 124, the annular elements being constructed of alternating struts and apices and the connecting members being constructed of a plurality of curved and straight segments, with an annular element being connected to an adjacent annular element by the connecting members as claimed. Note also with

respect to claim 1 and claims 12-13, the stent 122 as shown in Fig. 3C is inherently capable of maintaining a consistent length between the compressed and expanded states by constraining the ends of the stent as it is being expanded (or compressed) and allowing the connecting members 124 to be stretched out (or buckled inward) in a similar manner to that of the instant invention. With respect to claims 16-19 and 22-26, it can be seen that stent 122 is inherently capable of being configured as claimed, since each separate segment could be expanded to various diameters and therefore be configured to assume a tapered or stepped shaped as claimed. With respect to claim 27, it can be seen from Fig. 3C that the annular portion of the stent 122 comprising the connecting members 124 forms a "segment" of the stent and, therefore, would provide an area having a different degree of flexibility from the adjacent annular element. With respect to claims 29 and 31, it can be seen that the apertures defined by adjacent annular elements 102 and connecting members 124 are larger and geometrically different than the diamond-shaped apertures defined within the annular member and, therefore, provide segments having different degrees of flexibility.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

7. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchasik et al. As previously discussed, Pinchasik et al shows a device which is basically the same as that recited in claims 14 and 15. However, Pinchasik et al does not disclose making the stent out of shape memory alloy, and even seems to teach away from doing so by the disclosure in col. 2, lines 42-46 which states preference for "low memory, more plastic then elastic, bio-compatible materials." However, it is well known in the art that a shape memory alloy such as Nitinol is often chosen as a stent material because of its superior plastic deformation properties, and not necessarily only for its shape memory properties. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to choose a shape memory alloy as the material of manufacture, as this material has superior plastic deformation properties which would be highly desirable in a stent.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchasik et al in view of An et al (U.S. Pat. No. 5,545,211). As previously discussed, Pinchasik et al shows a device which is basically the same as that recited in claim 21. However, Pinchasik et al does not show the stent in combination with a biocompatible graft covering. Fig. 5 and the disclosure of col. 4, lines 1-12 of An et al teaches a stent having a biocompatible graft covering. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of An et al, to modify the device of Pinchasik et al to include a covering, as this configuration is well known in the art for preventing growth of tissue and restenosis.

9. The courts have concluded that there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). Also, references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969).

Allowable Subject Matter

10. Claim 20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Claims 28, 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip at (703) 308-3383. The examiner can normally be reached Mon-Fri from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Buiz, can be reached at (703) 308-0871. The fax number for this Unit is (703) 308-0758 or (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at (703) 308-0858.

DOR

DOR
October 21, 1997

MICHAEL BUIZ
SUPERVISORY PATENT EXAMINER
GROUP 3300
10/22/97